DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sensor, specified in claims 8, 9 and 10, and the controllable valve, specified in claim 12, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are also objected to because Figures 1A and 1B should be designated by a legend such as --Prior Art-- because only that which is old is illustrated.

See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are also objected to because: Figures 7A, 7B, and 7D contain handwritten alterations. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The specification uses inconsistent terminology to refer to characters which designate parts in the drawings. An example can be found on page 11, lines 2, 3, and 14 which all refer to character "20" by a different name.

Additionally, the specification is not consistent with nomenclature or referenced component when referring to either the same or different component having the word “interface" in its name. Examples include: page 6, lines 19 and 21; and page 7, lines 12 and 18.

Appropriate correction for all inconsistent terminology is required.

Claim Objections

Claims 1-30 are objected to because of the following informalities:

In the claims correct spelling and consistent terminology must be used for components and steps of apparatuses and methods to provide necessary antecedent basis.

For example, claim 1 recites the limitation “a nasal interface” in line 4, however and claim 8, dependant of claim 1, recites the limitation “the interface” in line 3, however, claim 9, dependant of claim 8, recites the limitation “the nasal interface unit" in line 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "additional inlet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 15-18 and 25-30 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1-10, 13, 15-18 and 22-27** of copending Application No. **10/522,073**. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both cover the same respiratory aid apparatus, which includes a nasal interface.

The limitations of claim 1 are found in claim 1 of 10/522,073. The limitations of claim 2 are found in claim 2 of 10/522,073. The limitations of claim 3 are found in claim 3 of 10/522,073. The limitations of claim 4 are found in claim 4 of 10/522,073. The limitations of claim 5 are found in claim 5 of 10/522,073. The limitations of claim 6 are found in claim 6 of 10/522,073. The limitations of claim 7 are found in claim 7 of 10/522,073. The limitations of claim 8 are found in claim 8 of 10/522,073. The limitations of claim 9 are found in claim 9 of 10/522,073. The limitations of claim 10 are found in claim 10 of 10/522,073.

The limitations of claim 11 are found in claim 12 of 10/522,073. The limitations of claim 12 are found in claim 13 of 10/522,073. The limitations of claim 15 are found in claim 15 of 10/522,073. The limitations of claim 16 are found in claim 16 of 10/522,073. The limitations of claim 17 are found in claim 17 of 10/522,073. The limitations of claim 18 are found in claim 18 of 10/522,073.

The limitations of claim 25 are found in claim 22 of 10/522,073. The limitations of claim 26 are found in claim 23 of 10/522,073. The limitations of claim 27 are found in claim 24 of 10/522,073. The limitations of claim 28 are found in claim 25 of 10/522,073. The limitations of claim 29 are found in claim 26 of 10/522,073. The limitations of claim 27 are found in claim 30 of 10/522,073.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1, 2, 4, 5, 7, 11-13, 15-17, 19, 21 and 25-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077).**

Regarding claim 1, Sherrod discloses a respiratory aid apparatus for administrating a controlled flow of respiratory gas to a user airways, the apparatus comprising: a source of a high pressure respiratory gas (18); an interface comprising at least one tubular member (28) defining an air passage to the user and at least one Venturi device (28) in fluid communication with said air passage, the Venturi device comprises:

A hollow member, defining a central space (46), having a first end (36) open to surrounding ambient air and a second open end (38) in fluid communication with air passage; and a first inlet port (44) opening into central space, the inlet is configured to direct compressed respiratory gas entering said central space toward the second end (column 4, lines 16-22); And a low cross-section flexible tubing (20, 24, and 26) connecting between the source of high pressure respiratory gas and said inlet of said Venturi device.

Sherrod fails to disclose that the interface is a nasal interface wherein the tubular member defines the air passage to the user's nostril.

However, Hofstetter et al. discloses a respiratory aid apparatus for administrating a respiratory gas to a user airway, the apparatus comprising a nasal interface (10, Abstract also).

3. It would have been obvious to one of ordinary skill in the art the modify the invention of Sherrod with a nasal interface as taught by Hofstetter et al. since doing so would allow the device to be used in settings where access to the mouth is needed.

Regarding claim 2, Sherrod discloses the respiratory gas to the user airway is air.

Regarding claim 4, Sherrod discloses the source of high pressure respiratory gas is a tank (18) containing high pressure respiratory gas, oxygen.

Regarding claim 5, Sherrod discloses the respiratory gas is oxygen (column 3, lines 25-36).

Regarding claim 7, Sherrod discloses the source of high pressure respiratory gas is provided with a regulator (22) for regulating the output pressure of said source.

Regarding claim 11, Sherrod discloses the Venturi device (28) further comprises a second inlet port (48) opening into said central space and wherein said second inlet is configured to direct compressed gas entering the central space toward the first end of assisting removal of air from the user's airways (column 4, lines 24-30).

Regarding claim 12, Sherrod discloses a controllable valve (22) for directing the compressed air alternately to the first inlet port during inhalation phase and to the second inlet port during exhalation phase (column 3, lines 28-36).

Regarding claim 13, Sherrod fails to discloses the nasal interface comprising two tubular members each defining an air passage to a user's nostril, the two air passages are in fluid communication via a common space and wherein said Venturi device is in fluid communication with said common space.

However, Hofstetter et al. teaches a nasal interface comprising two tubular members (130) defining an air passage to a user's nostril, the two air passages are in fluid communication via a common space (8, 12, and 14).

4. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a nasal interface as taught by Hofstetter et al., since doing so would allow the device to be used in settings where access to the mouth is needed.

Regarding claim 15, Sherrod discloses a user interface unit comprising at least one tubular member (28) defining an air passage to a user when in use and at least one Venturi device (28) in fluid communication with air passage, the Venturi device comprises: a hollow member, defining a central space (46), having a first end (36) open to surrounding ambient air and a second open end (38) in fluid communication with air passage; and a first inlet port (44) connectable via thin tubing (24) to a source of high pressure respiratory gas (18), the inlet opens into central space, the inlet is configured to direct compressed gas entering central space toward the second end.

Sherrod fails to disclose that the interface is a nasal interface wherein the tubular member defines the air passage to the user's nostril.

However, Hofstetter et al. discloses a respiratory aid apparatus for administrating a respiratory gas to a user airway, the apparatus comprising a nasal interface (10).

5. It would have been obvious to one of ordinary skill in the art the modify the invention of Sherrod with a nasal interface as taught by Hofstetter et al. since doing so would allow the device to be used in settings where access to the mouth is needed.

Regarding claim 16, Sherrod discloses the Venturi device (28) further comprises a second inlet port (48) opening into said central space and wherein said second inlet is configured to direct compressed gas entering the central space toward the first end of assisting removal of air from the user's airways (column 4, lines 24-30).

Regarding claim 17, Sherrod discloses a controllable valve (22) for directing the compressed air alternately to the first inlet port during inhalation phase and to the second inlet port during exhalation phase (column 3, lines 28-36).

Regarding claim 19, Sherrod in combination with Hoffstetter fail to disclose the nasal interface comprising two tubular members each defining an air passage to a user's nostril, the two air passages are in fluid communication via a common space and wherein Venturi device is in fluid communication with common space.

However, Hofstetter et al. teaches a nasal interface comprising two tubular members (130) defining an air passage to a user's nostril, the two air passages are in fluid communication via a common space (8, 12, and 14).

6. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a nasal interface as taught by Hofstetter et al., since doing so would allow the device to be used in settings where access to the mouth is needed.

Regarding claim 21, Sherrod discloses the Venturi device (28) further comprises a second inlet port (48) opening into said central space and wherein said second inlet is configured to direct compressed gas entering the central space toward the first end of assisting removal of air from the user's airways (column 4, lines 24-30).

Regarding claim 25, Sherrod discloses a method for supplying a controlled pressure of respiratory gas of to a user, the method comprising: delivering a high pressure respiratory gas via a thin tubing (20, 24, and 26) to a user interface (30); and accelerating the high pressure respiratory gas upon entering the user interface by means of a Venturi device (28), the Venturi device is configured to direct flow of compressed air toward the user airways, the Venturi device is having an end open to surrounding ambient air (36); thereby pumping ambient air into the user interface, but fails to teach the user interface being a nasal user interface.

However, Hofstetter et al. discloses a respiratory aid method for administrating a respiratory gas to a user airway, the method using a user nasal interface (10).

7. It would have been obvious to one of ordinary skill in the art the modify the method of Sherrod with a user nasal interface as taught by Hofstetter et al. since doing so would allow the method to be used in settings where access to the mouth is needed.

Regarding claim 26, Sherrod discloses method of claim 25 wherein the respiratory gas is air.

Regarding claim 27, Sherrod discloses controlling the pressure of the high pressure respiratory gas delivered to the user interface by means of a regulator valve (22).

Regarding claim 28, Sherrod discloses stopping the delivery of high pressure respiratory gas during exhalation phase (column 3, lines 32-36).

Regarding claim 29, Sherrod discloses the Venturi device is provided with an inlet configured to direct compressed air toward the end open to ambient air and wherein the method further comprising delivering the high pressures respiratory gas to said additional inlet for assisting removal of air from the user airways during exhalation phase (column 3, lines 32-36; column 4, lines 16-30

Regarding claim 30. Sherrod discloses the use of a Venturi device (28) incorporated into a user interface unit in fluid communication with a user airways for administrating a controlled pressure of air to the user, but fails to teach the user interface unit being a user nasal interface unit.

However, Hofstetter et al. discloses a respiratory aid method for administrating a respiratory gas to a user airway, the method using a user nasal interface unit (10).

8. It would have been obvious to one of ordinary skill in the art the modify the method of Sherrod with a user nasal interface unit as taught by Hofstetter et al. since doing so would allow the method to be used in settings where access to the mouth is needed.

9. **Claims 3, 8, 9, 10 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077)** as applied to claims above, and further in view of **Hill (US 6,629,525 B2)**.

Regarding claim 3, Sherrod invention, as modified by Hofstetter, fails to disclose the source of high pressure respiratory gas is an oil-less air compressor.

However, Hill et al. discloses respiratory aid apparatus that delivers respiratory gas to a user airways using an oil-less air compressor (112) (column 6, lines 25-28).

10. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include an oil-less air compressor as taught by Hill, since doing so would prevent the possibility of oil from entering the air flow to the user.

Regarding claim 8, Sherrod invention, as modified by Hofstetter, fails to disclose for at least one sensor for detecting respiratory cycle of the user and with at least one controller for controlling the pressure of compressed gas entering the interface unit via the first inlet port, in accordance with said sensor.

However, Hill teaches at least one sensor adapted to sense one or more conditions indicative of the gas needs of the user, and a controller for controlling administration of gas supplied to user in accordance with sensor (Abstract)

11. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a sensor that detects respiratory cycle, which is a condition indicative of the gas needs of the user, as taught by Hill, since doing so would allow the alternating inhalation and exhalation phases, taught by Sherrod, to sync with the user's breath rate.

Regarding claim 9, Sherrod invention, as modified by Hofstetter and Hill, fails to specify a location for the sensor.

12. It would have been obvious to one of ordinary skill in the art to place a sensor intended for detecting respiratory cycle in the nasal interface unit, since this is the only part of the invention in communication with user airways.

Regarding claim 10, Sherrod invention, as modified by Hoffstetter and Hill, discloses a sensor (150) selected from a sound transducer, a pressure detector, a temperature detector or a humidity detector (column 10, lines 26-33).

Regarding claim 18, Sherrod invention, as modified by Hoffstetter, fails to disclose at least one sensor for detecting respiratory cycle of the user and with at least one controller for controlling the pressure of compressed gas entering the interface unit via the first inlet port, in accordance with said sensor.

However, Hill teaches at least one sensor adapted to sense one or more conditions indicative of the gas needs of the user, and a controller for controlling administration of gas supplied to user in accordance with sensor (Abstract)

13. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a sensor that detects respiratory cycle, which is a condition indicative of the gas needs of the user, as taught by Hill, since doing so would allow the alternating inhalation and exhalation phases, taught by Sherrod, to sync with the user's breath rate.

14. **Claims 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077)** as applied to claim 1 above, and further in view of **Boussignac (US 6,363,935 B1)**.

Regarding claim 6, Sherrod invention, as modified by Hoffstetter, fails to disclose the tubing diameter is in the range of 2-5 mm and wherein the pressure delivered to the nasal interface is in the range of 2- 6 atmospheres.

However, Boussignac discloses a respiratory aid apparatus comprising of a Venturi device with various tube sizes (column 4, lines 16-18) that meet and exceed the limits of the claim and can be varied in dimension and construction depending on user size and desired pressure (column 5, lines 13-20)

15. It would have been obvious to one of ordinary skill in the art to further modify the teachings of Sherrod to include the types of tubes taught by Boussignac since these are the types of tubes already used in respiratory devices (Boussignac column 5, lines 13-15) which would make the device easier to manufacture.

16. **Claims 14 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077)** as applied to claims above, and further in view of **Moa (US 5,193,532)**.

Regarding claim 14, Sherrod invention, as modified by Hofstetter, fails to disclose two tubular members each defining an air passage to a user's nostril and two Venturi devices, eachin fluid communication with one of the two air passages.

However, Moa et al. teaches a device for providing a continuous positive airway pressure with two tubular members and Venturi systems each comprising of a hollow

member (10), a firest end (12) open to surrounding ambient air, a second open end (11) which can be fitted to a patient's nose (column 2, lines 44-46) and a first inlet port (13) opening into central space, the inlet is configured to direct fresh gas toward second opening (fig. 1).

17. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include two tubular members and two Venturi devices as taught by Moa, since doing so would allow each nostril to be treated individually.

Regarding claim 22, Sherrod invention, as modified by Hofstetter, fails to disclose two tubular members and two Venturi devices.

However, Moa et al. teaches a device for providing a continuous positive airway pressure with two tubular members and two parallel Venturi systems each comprising of a hollow member (10), a first end (12) open to surrounding ambient air, a second open end (11) which can be fitted to a patient's nose (column 2, lines 44-46) and a first inlet port (13) opening into central space, the inlet is configured to direct fresh gas toward second opening (fig. 1).

18. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include tubular members and two Venturi devices as taught by Moa, since doing so would allow each nostril to be treated individually.

19. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view **Hofstetter (US 5,975,077)** as applied to claim 19 above, and further in view of **Goldstein (US 5,752,510)**.

Regarding claim 20, Sherrod invention, as modified by Hofstetter, fails to disclose a mouth piece mounted in such a way that when the mouth piece is inserted into the user mouth, each of the two tubular members is insertable into one of the user's nostrils.

However, Goldstein teaches a breathing apparatus with two tubular members (22 and 23) defining an air passage to a user's nostril, which is anchored to the user with a mouth piece (25), which helps with various breathing disorders (column 4, lines 7-18).

20. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a mouth piece as taught by Goldstein, since doing so would be beneficial in alleviating breathing disorders during sleep.

21. **Claim 23** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077)** and **Moa (US 5,193,532)** as applied to claim 22 above, and further in view of **Goldstein (US 5,752,510)**.

Regarding claim 23, Sherrod invention, as modified by Hofstetter and Moa, fails to disclose a mouth piece mounted in such a way that when the mouth piece is inserted into the user mouth, each of the two tubular members is insertable into one of the user's nostrils.

However, Goldstein teaches a breathing apparatus with two tubular members (22 and 23) defining an air passage to a user's nostril, which is anchored to the user with a mouth piece (25), which helps with various breathing disorders (column 4, lines 7-18).

22. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to include a mouth piece as taught by Goldstein, since doing so would be beneficial in alleviating breathing disorders during sleep.

23. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sherrod (US 5,979,444)** in view of **Hofstetter (US 5,975,077)** as applied to claim 15 above, and further in view of **McGlothen (US 6,536,436 B1)**.

Regarding claim 24, Sherrod invention, as modified by Hofstetter, fails to disclose the user interface strapped to the user head by the thin tubing delivering the compressed gas into the user interface.

However, McGlothen discloses a user nasal interface (30) strapped to a user head by the tubing (35) delivering the compressed gas in the user interface.

24. It would have been obvious to one of ordinary skill in the art to further modify the invention of Sherrod to use the tubing as a method to secure the interface to the user head as taught by McGlothen, since doing so would provide a simple way of securing interface to user head.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitations of the applicant's claimed and disclosed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Blizzard whose telephone number is (571)-

270-7138. The examiner can normally be reached on Monday-Thursday 7:30 AM - 6:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797.

10/23/08
/C. B./
Examiner, Art Unit 4185
/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4185